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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,882	12/27/2001	Dale R. Pfost	P-OD 5078	2031

41552 7590 10/18/2005

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/034,882	Applicant(s) PFOST, DALE R.	
	Examiner Carla Myers	Art Unit 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *23 June 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-27*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER

Continuation of 5. Applicant's reply has overcome the following rejection(s): the rejection under 112 second paragraph of claims 17 and 21 over the recitation of "further comprising observing...".

Continuation of 11. does NOT place the application in condition for allowance because: for the reasons of record. Applicants arguments regarding the 112 first and second paragraph rejections were addressed fully in the previous Office action. In summary, the previous rejections are maintained because the specification and claims do not describe a single embodiment of the claimed compositions with respect to their specific structure and do not provide sufficient guidance to make and use the claimed compositions. The response states that compounds suitable for inclusion in the compositions have been disclosed at page 4 of the specification. However, page 4 of the specification does not describe any particular compounds in terms of their specific structure or function. Rather, page 4 generically discusses the use of any drug, pharmaceutically active natural product or dietary supplement or any other compound or agent that could be used to treat a pathology. Such a disclosure is not equivalent to teaching specific compounds defined in terms of their chemical structure and specific functional properties which act to modulate the activity of one or more specific SNPs associated with particular pathologies. The response asserts that the specification provides considerable teachings and guidance to detect SNPs in the population, to perform the research required to determine whether an SNP is associated with a pathology, and the research required to then identify compounds that function to modulate the activity of a SNP. This argument has been fully considered but is not persuasive. While it is agreed that at the time the invention was made the general methodologies for sequencing genes and studying the association between a SNP and a pathology were known in the art, such methodologies provide only the research tools that could be utilized to try to discover new SNPs and an association between the SNPs and pathologies. Such methodologies do not provide a predictable means for identifying a representative number of compositions comprising specific compounds which have the effect of modulating target molecules associated with SNPs. Providing the outlines of a research project and discussing art conventional techniques for performing research is not equivalent to providing sufficient guidance to enable one of skill in the art to make and use compositions that effectively treat pathologies. Again, the claims are not drawn to methods of searching for SNPs or methods of searching for compounds that modulate targets associated with SNPs. Rather, the claims are drawn to the compositions themselves. It is maintained that the novel aspect of the invention is the identity of the particular compounds present in the compositions. Yet, the specification does not teach the identity of any compounds which fall within the scope of the claims. With respect to the 112 second rejection, the response states that the specification clearly teaches that a target molecule is considered associated with a SNP if the target molecule has a measurable characteristic. This argument is not persuasive. Firstly, the specification does not specifically provide such a definition for this phrase. Secondly, the specification does not define a measurable characteristic and does not teach what would be encompassed by a measurable characteristic in order to allow one to ascertain what was intended to be encompassed by target molecules associated with a SNP. Thereby, it is maintained that one cannot determine the meets and bounds of the claimed subject matter. The response further states that the phrase "position corresponding" is clear and that this phrase refers to the same position of the SNP or an amino acid residue encoded by a codon that encompasses the SNP. However, this definition is not set forth in the specification as originally filed, the phrase does not have this limited meaning in the art and the claims are not limited to this specific embodiment. If Applicants intend for the claims to be limited to this subject matter, then the claims should recite this specific limitation. With respect to the 102 rejection over Hurwitz, Applicants state that the Office action has not clearly pointed out how the vaccines modulate themselves, indirectly or directly. This argument is not persuasive because Applicants are arguing limitations that are not recited in the claims. The claims do not require that the vaccines/compounds modulate themselves directly or indirectly. The claims require a composition containing compounds that modulate a target molecule that is by some means associated with a SNP. Hurwitz teaches vaccine compositions comprising HIV proteins that contain SNPs. The vaccines of Hurwitz stimulate antibody production or cellular immunity against the HIV antigens and thereby modulate the activity of a target molecule associated with a SNP. The vaccines of Hurwitz are effective at treating a patient with a pathology (HIV infection or susceptibility to HIV infection). Thereby, it is maintained that the vaccines of Hurwitz meet each of the limitations recited in the claims and anticipate the claimed invention. With respect to the 102 rejection over Ostberg et al, it is noted that Applicants previous response did not address this rejection. New arguments were provided after final rejection. Applicants assert that Ostberg speculates that a SNP could potentially encode for a single amino acid difference but that such teachings "fall short of providing an enabling reference." It is noted that this argument is inconsistent with Applicant's assertions that they have fully enabled all possible compositions containing compounds that modulate any target molecule associated with any SNP and effective to treat any pathology, while the specification itself only speculates on the existence of such compounds. Irrespective of this inconsistency, it is maintained that Ostberg does in fact teach that the HBV antibodies bind to HBV proteins having a point mutation and teaches that the compositions are effetive for treating HBV infections or susceptibility to HBV infections. Applicants response does not provided any evidence or scientific arguments to contradict these teachings of Ostberg. Further, Ostberg clearly exemplifies the amino acid changes in the HBV proteins and the antibodies directed against the epitopes containing these amino acid changes (see col. 3 lines 5-48, and Tables 8-1, 8-2, 8-3 and 8-4). Thereby, the Ostberg patent is in fact a fully enabling reference.